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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,013	08/13/2008	Carolina Baten	0470-062779	6492

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EXAMINER
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KING, FELICIA C

ART UNIT	PAPER NUMBER
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1789

NOTIFICATION DATE	DELIVERY MODE
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03/17/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@webblaw.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/593,013	<b>Applicant(s)</b> BATEN ET AL.	
	<b>Examiner</b> FELICIA C. KING	<b>Art Unit</b> 1789	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date. _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

**This Office Action is written in response to Applicants Remarks filed 1/14/11. Claims 10-21 are pending.**

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 14 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase " fermenting is continued for at least one hour longer time than the time normally required for optimal growth of the fermenting microorganism " in claims 14 and 18 is relative which renders the claim indefinite. Optimal growth can vary from microorganism to microorganism. The Office cannot ascertain the time normally required for optimal growth of fermenting microorganisms especially since there is no particular microorganism recited in claims 10 and 16 upon which claims 14 and 18 depend respectively. Appropriate correction, clarification, or cancellation of the claim is required.

#### ***Claim Rejections - 35 USC § 103***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. **Claims 10-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuter (US 3,326,693) in view of Tolton II et al. (US 6,514, 941) and Kwon (EP 0406 598).**

**Regarding Claims 10, 11, 12, 13, 15:** Reuter discloses a process for mixing casein peptone (hydrolyzed casein) with sterile milk and then inoculating the milk with *Lactobacillus acidophilus* [col. 2,

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lines 30-49] to produce sour milk products. Reuter discloses that the presence of hydrolyzed casein enhances the proliferation of *Lactobacillus acidophilus* [col. 2, lines 41-45]. Reuter does not disclose that the casein hydrolysate has an angiotensin-I-converting enzyme inhibiting property (ACE or ACEI). Reuter does not disclose de-bittered food.

Tolton II discloses a process for preparing a protein hydrolysate that has an angiotensin-I-converting enzyme inhibiting property (ACE or ACEI) and more specifically that the protein hydrolysate is a casein hydrolysate that has C6, C7, and or C12 peptides [col. 2, lines 46-58; col. 3, lines 6-18; col. 4, lines 63-67]. Tolton also discloses that the composition can be incorporated into beverages and yogurt [col. 5, lines 1-10].

Kwon discloses a process for debittering hydrolyzed protein such as casein by fermenting it with microorganisms that produce peptidases [abstract; col. 1, lines 1-4; col. 2, lines 1-5]. Kwon discloses that when proteins are hydrolyzed enzymatically, a bitter taste is retained because the protease used in the hydrolyzation process rarely goes to completion [col. 1, lines 5-17]. Kwon discloses incubating a hydrolyzed protein with a culture of a peptidase producing food grade microorganism, and that the process results in the hydrolysis of bitter polypeptides to give a debittered substance [col. 1, lines 51-58]. Kwon discloses that bacteria belonging to streptococci or lactobacilli are capable of debittering hydrolyzed protein [col. 2, lines 15-21].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Reuter, Tolton II, and Kwon before him or her to substitute the hydrolyzed casein of Reuter for the hydrolyzed casein of Tolton II in order to form a sour milk or a sour milk product that is capable of having an antihypertensive effect while enhancing the growth of *L. acidophilus*. This is especially beneficial for the consumer since beverages like sour milk and its

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products such as yogurt, already provide known health benefits for the digestive tract and immune system.

Since Tolton II discloses that the casein hydrolysate having ACE or ACEI properties can be included in beverages and yogurt, since the hydrolyzed casein in Tolton II is a casein peptone similar to what is disclosed in Reuter, and since Reuter discloses that the incorporation of casein peptone in the production of sour milk and yogurt is advantageous for its ability to enhance the growth of fermenting microorganisms, it would have been obvious to one of ordinary skill in the art to substitute the casein peptone (hydrolyzed casein) of Reuter for the hydrolyzed casein of Tolton II in order to get the effects of the proliferation of *L. acidophilus* during the fermentation of the milk and the health benefits provided by the antihypertensive effects.

Further, it would have been obvious to one of ordinary skill in the art to subject the hydrolyzed casein disclosed in Tolton II to fermentation with a member of streptococci or lactobacilli as discussed in Kwon, in order to de-bitter the hydrolyzed protein at some point in the production of the food ingredient or food product. De-bittering would have been obvious because it would have helped ensure that the bitter tastes were not present and to therefore ensure that the consumer does not experience organoleptically undesirable flavors in the food.

Alternatively, it would have been obvious to one of ordinary skill in the art having the teachings of Reuter, Tolton II, and Kwon that the fermentation of the hydrolyzed casein which occurs in the combination of Reuter, Tolton II would have resulted in a debittered food product since the starting product contains a mixture of hydrolyzed casein as is disclosed in all three references and since Reuter discloses fermenting a hydrolyzed casein containing material with *L. acidophilus* and Kwon discloses that microorganisms selected from streptococci and lactobacilli are capable of de-bittering hydrolyzed casein.

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**Regarding Claim 14:** Reuter discloses fermenting milk with *L. acidophilus* for 12 to 20 hours. Reuter does not disclose that the “fermenting is continued for a time that is at least one longer than the time normally required for optimal growth of the fermenting microorganism” as recited in claim 14.

However, it would have been obvious to modify the fermentation time based on the desired taste or the expression of particular components that are produced by the fermentation process since it has been held that the provision of adjustability, where needed, involves only routine skill in the art, *In re Stevens*, 101 USPQ 284 (CCPA 1954).

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the length of fermentation of the inoculated milk for the production of fermented milk and for the expression of desired properties such as flavor, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Also see 112 2<sup>nd</sup> rejection of claim 14.

5. **Claims 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Masuyama et al. (EP 1018341) in view of Klaver et al. (US 4,938, 973) and Kwon (EP 0406 598).**

**Regarding Claims 16, 17, and 19-21:** Masuyama discloses using milk as a starting food material and enzymatically hydrolyzing the starting food material with enzymes derived from microorganisms, chemicals, or enzyme hydrolysis that are capable of producing peptides that have angiotensin converting enzyme inhibitory activity [0017, 0018, 0019, 0024]. Masuyama discloses *Streptococcus thermophilus*, *Lactobacillus bulgaricus*, *Lactobacillus acidophilus*, and *Lactobacillus casei* as fermenting microorganisms that are capable of producing peptides that have angiotensin converting

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enzyme inhibitory activity [0020]. Masuyama discloses functional foods of the invention being yogurt, acidified milk, or fermented sour milk [0034]. Although Masuyama discloses the previously recited functional foods, Masuyama does not explicitly disclose that after enzymatically hydrolyzing the milk via microorganisms, more fermenting microorganisms are further added to the milk and is then again fermented.

Klaver discloses inoculating raw milk with *Streptococcus thermophilus* or *Lactobacillus bulgaricus* to make yogurt or fermented milk [col. 2, lines 55-67; col.8, lines 47-68, col. 9, lines 9-30]. Klaver also discloses *L. acidophilus* for the production of acidophilus milk [col. 2, lines 20-25].

At the time of the invention it would have been obvious to one of ordinary skill in the art having the teachings of Masuyama, Klaver, and Kwon before him or her to incorporate or substitute the treated milk of Masuyama, having angiotensin converting enzyme inhibitory activity, in or for the raw milk of Klaver in order to provide a fermented food product that has an antihypertensive effect.

It would have further been obvious to incorporate or substitute the milk since Masuyama anticipates the use of the treated milk in fermented foods such as yogurt and acidified milk. This is especially beneficial for the consumer since foods such as sour milk and its products such as yogurt already provide known health benefits for the digestive tract and immune system.

Further, it would have been obvious to one of ordinary skill in the art having the teachings of Masuyama, Klaver, and Kwon that the fermentation of the milk (containing casein) which occurs in the combination of Masuyama and Klaver would have resulted in a debittered food product since the starting product contains a mixture of lactobacilli or streptococci inoculated in milk or other protein substrate as is disclosed in all three references, since Masuyama discloses fermenting milk substrates with *Streptococcus thermophilus*, *Lactobacillus bulgaricus*, *Lactobacillus acidophilus*, and *Lactobacillus*

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*casei*, and since Kwon discloses that microorganisms selected from streptococci and lactobacilli are capable of de-bittering hydrolyzed casein.

**Regarding Claim 18:** Masuyama discloses hydrolyzing protein in milk as discussed above. Masuyama does not disclose that “fermenting is continued for a time that is at least one hour longer than the time normally required for optimal growth of the fermenting microorganism” as recited in claim 18. Klaver discloses fermenting milk with *Streptococcus thermophilus* or *Lactobacillus bulgaricus* separately for 39 hours [col. 8, Ex. V].

Although Matsuyama and Klaver do not disclose the time for fermentation as recited in claim 18, it would have been obvious to modify fermentation time based on the desired taste or the expression of particular components that are produced by the fermentation process since it has been held that the provision of adjustability, where needed, involves only routine skill in the art, *In re Stevens*, 101 USPQ 284 (CCPA 1954).

Further, it would have been obvious to one having ordinary skill in the art at the time of the invention to adjust the length of fermentation of the inoculated milk for the production of fermented milk, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272.

Also see 112 2<sup>nd</sup> rejection of claim 18.

### ***Response to Arguments***

6. Applicant’s arguments, filed 1/14/11, with respect to the rejections of claim 10-21 under the prior art rejections made in the previous Office Action have been fully considered and are persuasive in light of amendments made to the claims. Therefore, the rejection has been withdrawn. However, upon further consideration, new grounds of rejection are made in view of the prior art rejections made above.



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*Conclusion*

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

**Nakamura et al. (US 5,449,661)** discloses removal of bitter tastes from peptides containing ACE inhibitor properties, by column chromatography or biochemical methods [col. 1., lines 65-68; col. 2, lines 1-3].

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **FELICIA C. KING** whose telephone number is (571)270-3733. The examiner can normally be reached on Mon- Thu 7:30 a.m.- 5:00 p.m.; Fri 7:30 a.m. - 4:00 p.m. alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jennifer McNeil can be reached on 571-272-1540. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/F. K./

Examiner, Art Unit 1789

/Timothy M. Speer/

Primary Examiner, Art Unit 1784